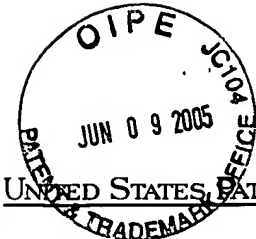


JFW



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/763,539	01/26/2004	Stephen J. Karlik	002010-854

CONFIRMATION NO. 9237

FORMALITIES LETTER



OC000000015873445

21839

BURNS DOANE SWECKER & MATHIS L L P
 POST OFFICE BOX 1404
 ALEXANDRIA, VA 22313-1404

Date Mailed: 04/26/2005

NOTICE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

A filing date has been accorded to the above-identified nonprovisional application papers; however, the following item(s) appear to have been omitted from the application:

- Page(s) **346** of the specification (description and claims).

I. Should applicant contend that the above-noted omitted item(s) was in fact deposited in the U.S. Patent and Trademark Office (USPTO) with the nonprovisional application papers, a copy of this Notice and a petition (and \$400.00 petition fee (37 CFR 1.17(f))) with evidence of such deposit **must** be filed within **TWO MONTHS** of the date of this Notice. The petition fee will be refunded if it is determined that the item(s) was received by the USPTO.

II. Should applicant desire to supply the omitted item(s) and accept the date that such omitted item(s) was filed in the USPTO as the filing date of the above-identified application, a copy of this Notice, the omitted item(s) (with a supplemental oath or declaration in compliance with 37 CFR 1.63 and 1.64 referring to such items), and a petition under 37 CFR 1.182 (with the \$400.00 petition fee (37 CFR 1.17(f)) requesting the later filing date **must** be filed within **TWO MONTHS** of the date of this Notice.

Applicant is advised that generally the filing fee required for an application is the filing fee in effect on the filing date accorded the application and that payment of the requisite basic filing fee on a date later than the filing date of the application requires payment of a surcharge (37 CFR 1.16(f)). To avoid processing delays and payment of a surcharge, applicant should submit any balance due for the requisite filing fee based on the later filing date being requested when submitting the omitted item(s) and the petition (and petition fee) requesting the later filing date.

III. The failure to file a petition (and petition fee) under the above options (I) or (II) within **TWO MONTHS** of the date of this Notice (37 CFR 1.181(f)) will be treated as a constructive acceptance by the applicant of the application as deposited in the USPTO. **THIS TWO MONTH PERIOD IS NOT EXTENDABLE UNDER 37 CFR 1.136(a) or (b).** In the absence of a timely filed petition in reply to this Notice, the application will maintain a filing date as of the date of deposit of the application papers in the USPTO, and original application papers (i.e., the original disclosure of the invention) will include only those application papers present in the USPTO on the date of deposit.

In the event that applicant elects not to take action pursuant to options (I) or (II) above (thereby constructively electing option (III)), amendment of the specification to renumber the pages consecutively and cancel incomplete sentences caused by any omitted page(s), and/or amendment of the specification to cancel all references to any omitted drawing(s), relabel the drawing figures to be numbered consecutively (if necessary), and correct the

references in the specification to the drawing figures to correspond with any relabeled drawing figures, is required. A copy of the drawing figures showing the proposed changes in red ink should accompany with any drawing changes. Such amendment and/or correction to the drawing figures, if necessary, should be by way of preliminary amendment submitted prior to the first Office action to avoid delays in the prosecution of the application.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

*A copy of this notice **MUST** be returned with the reply.*



Office of Initial Patent Examination (703) 308-1202

PART 2 - COPY TO BE RETURNED WITH RESPONSE



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Steve J. Karlik et al.

Application No.: 10/763,539

Filing Date: January 26, 2004

Title: COMPOSITION FOR AND TREATMENT OF DEMYELINATING DISEASES AND PARALYSIS BY
ADMINISTRATION OF REMYELINATING AGENTS

Group Art Unit:

Examiner:

Confirmation No.: 9237

AMENDMENT/REPLY TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed is a reply for the above-identified patent application.

- ☐ A Petition for Extension of Time is also enclosed.
- ☐ Terminal Disclaimer(s) and the ☐ \$65.00 (2814) ☐ \$130.00 (1814) fee per
Disclaimer due under 37 C.F.R. § 1.20(d) are also enclosed.
- ☒ Also enclosed is/are Copy of page 346 of the specification as filed on January 26, 2004; copy of
date-stamped postcards; and copy of Notice of Omitted Item(s) in a Nonprovisional Application

- ☐ Small entity status is hereby claimed.
- ☐ Applicant(s) requests continued examination under 37 C.F.R. § 1.114 and enclose the
☐ \$395.00 (2801) ☐ \$790.00 (1801) fee due under 37 C.F.R. § 1.17(e).
- ☐ Applicant(s) requests that any previously unentered after final amendments not be entered.
Continued examination is requested based on the enclosed documents identified above.
- ☐ Applicant(s) previously submitted _____

on _____
for which continued examination is requested.
- ☐ Applicant(s) requests suspension of action by the Office until at least _____,
which does not exceed three months from the filing of this RCE, in accordance with 37 C.F.R.
§ 1.103(c). The required fee under 37 C.F.R. § 1.17(i) is enclosed.
- ☐ A Request for Entry and Consideration of Submission under 37 C.F.R. § 1.129(a) (1809/2809) is also
enclosed.

- ☒ No additional claim fee is required.
- ☐ An additional claim fee is required, and is calculated as shown below.

AMENDED CLAIMS					
	No. of Claims	Highest No. of Claims Previously Paid For	Extra Claims	Rate	Additional Fee
Total Claims		MINUS =	0	x \$50.00 (1202) =	\$ 0.00
Independent Claims		MINUS =	0	x \$200.00 (1201) =	\$ 0.00
If Amendment adds multiple dependent claims, add \$360.00 (1203)					
Total Claim Amendment Fee					\$ 0.00
<input type="checkbox"/> Small Entity Status claimed - subtract 50% of Total Claim Amendment Fee					\$ 0.00
TOTAL ADDITIONAL CLAIM FEE DUE FOR THIS AMENDMENT					\$ 0.00

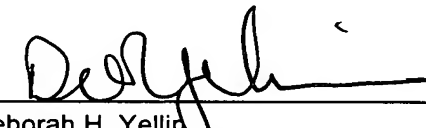
- ☐ A check in the amount of _____ is enclosed for the fee due.
- ☐ Charge _____ to Deposit Account No. 02-4800.
- ☐ Charge _____ to credit card. Form PTO-2038 is attached.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17, 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By


 Deborah H. Yellin
 Registration No. 43,904

Date: June 9, 2005



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
Steve J. Karlik et al.)	Group Art Unit: Unassigned
Application No.: 10/763,539)	Examiner: Unassigned
Filed: January 26, 2004)	Confirmation No.: 9237
For: COMPOSITION FOR AND)	
TREATMENT OF DEMYELINATING)	
DISEASES AND PARALYSIS BY)	
ADMINISTRATION OF)	
REMYELINATING AGENTS)	

**RESPONSE OF OMITTED ITEM(S) IN A NONPROVISIONAL APPLICATION
FILED UNDER 37 C.F.R. § 1.53(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notice of Omitted Item(s) in a Nonprovisional Application
Filed Under 37 C.F.R. § 1.53(b), dated April 26, 2005, Applicants submit he
following:

Page 346 of the specification that was purportedly
omitted from the application when filed on January 26, 2004.

Applicants state that the specification, as filed, on January 26, 2004 did
contain page 346, which is attached hereto for the convenience of the office. A copy
of the stamped postcards, to this effect, dated January 26, 2004 is also attached
showing the complete specification was acknowledged as filed. In the event there
are any questions pertaining to this Response, the undersigned can be reached at
the number below.

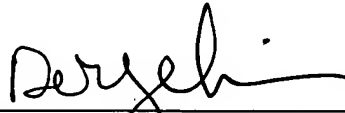
No fee is believed necessary. However, the Director is hereby authorized to charge any appropriate fees that may be required by this paper, and credit any overpayment, to Deposit Account No. 02-4800. This paper is submitted in duplicate.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: June 9, 2005

By:



Deborah H. Yellin
Registration No. 45,904

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620



- 3.35 (m, 1H), 3.26 - 3.19 (m, 1H), 3.12 - 2.97 (m, 8H), 2.06 - 2.03 (m, 1H), 1.66 - 1.57 (m, 3H), 1.26 (d, 6H).

¹³C NMR (CDCl₃): δ 170.50, 170.40, 154.90, 153.60, 150.70, 150.30, 133.30, 132.90, 130.10, 125.00, 121.80, 121.80, 118.50, 112.80, 69.60, 62.20, 53.20, 49.60, 37.10, 36.60, 36.30, 30.10, 24.20, 21.59, 21.56.

Example 184

Synthesis of

N-(3,4-Difluorobenzenesulfonyl)-L-prolyl-4-(*N,N*-dimethylcarbamyloxy)phenylalanine

The title compound was prepared from the product of Example 183 using the procedure described in Method 7.

NMR data was as follows:

¹H NMR (CD₃OD): δ 8.10 (d, 1H), 7.84 - 7.77 (m, 1H), 7.69 - 7.65 (m, 1H), 7.53 - 7.45 (m, 1H), 7.28 (d, 2H), 7.02 (d, 2H), 4.72 - 4.68 (m, 1H), 4.19 - 4.16 (m, 1H), 3.43 - 3.39 (m, 1H), 3.31 - 3.21 (m, 2H), 3.13 - 3.05 (m, 4H), 2.97 (s, 3H), 1.86 - 1.61 (m, 4H).

¹³C NMR (CD₃OD): δ 174.2, 174.1, 164.7, 156.9, 154.9, 152.0, 151.6, 135.8, 135.6, 131.6, 129.7, 122.9, 119.7, 118.8, 63.1, 54.7, 50.5, 37.4, 36.8, 36.6, 31.9, 25.5.

Example 185

Synthesis of

N-(3,4-Difluorobenzenesulfonyl)-L-(1,1-dioxothiamorpholin-3-carbonyl)-L-4-(*N,N*-dimethylcarbamyloxy)phenylalanine *tert*-Butyl Ester

The title compound was prepared using the procedure described in Example 92 by substitution of the appropriate starting materials.

NMR data was as follows:

¹H NMR (CDCl₃): δ 7.71 (m, 2H), 7.33 (m, 1H), 7.07 (d, 2H), 6.91 (d, 2H), 6.36 (d, 1H), 4.95 (m, 1H), 4.61 (m, 1H), 4.03 (m, 2H), 3.16 (m, 2H), 3.13 (m, 4H), 3.07 (m, 1H), 2.93 (s, 9H), 1.43 (s, 9H).

**New Patent Application Postcard**Inventor: Steve J. KARLIK et al.Appln. No.: UnassignedDocket No.: 002010-854Working Atty.: MMH/gjsDate: January 26, 2004Title: COMPOSITION FOR AND TREATMENT OF DEMYELINATING DISEASES AND PARALYSIS BY ADMINISTRATION OF REMYELINATING AGENTS

48

Dkt. Clerk Initials



The following was/were received in the U.S. Patent and Trademark Office on the date stamped hereon:

- ☒ Utility Patent Application Transmittal
☐ Design Patent Application Transmittal
☐ Continuing Prosecution Application Request
☐ Continuing/Divisional Application (Rule 1.53(b)) with copy of application
☐ Provisional Application Cover Sheet
☐ Provisional Application Transmittal
☐ Request for Continued Examination

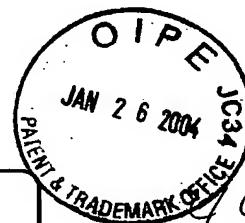
INCLUDING:

- ☒ Specification (pages 1 - 555)
☒ Claims (claims(s) 1 - 89 , 92 pgs.)
☒ Drawings (Fig(s). 1 - 18b , 25 pgs.)
☒ Abstract of the Disclosure

- ☐ Executed Declaration/Power of Attorney
☒ Unexecuted Declaration/Power of Attorney
☐ Assignment/Assignment Recordation Form Cover Sheet (PTO-1595)
☐ Submission of Certified Copy of Priority Document w/ certified copy(ies)
☐ Preliminary Amendment
☐ Information Disclosure Statement Transmittal
☐ Information Disclosure Citation (PTO-1449)
☐ Information Disclosure Statement w/ document(s)
☐ Petition for Month Extension of Time
☐ Gen. Authorization for Petition for Ext. of Time and Pymt. of Fees
☐ Patent Application Data Sheet

- ☒ Check for \$ 4,370.00 is enclosed
☐ Check for \$ _____ is enclosed
☐ Charge \$ _____ to Deposit Account

If submitting documents via Express Mail, provide the Express Mailing Label No. below:
Express Mail Mailing Label No.

(9)
(2)**New Patent Application Postcard**Inventor: Steve J. KARLIK et al.Appln. No.: UnassignedDocket No.: 002010-854Working Atty.: MMH/gjsDate: January 26, 2004Title: COMPOSITION FOR AND TREATMENT OF DEMYELINATING DISEASES AND PARALYSIS BY ADMINISTRATION OF REMYELINATING AGENTS

Dkt. Clerk Initials



The following was/were received in the U.S. Patent and Trademark Office on the date stamped hereon:

- ☒ Utility Patent Application Transmittal
☐ Design Patent Application Transmittal
☐ Continuing Prosecution Application Request
☐ Continuing/Divisional Application (Rule 1.53(b)) with copy of application
☐ Provisional Application Cover Sheet
☐ Provisional Application Transmittal
☐ Request for Continued Examination

INCLUDING:

- ☒ Specification (pages 1 - 555)
☒ Claims (claims(s) 1 - 89 , 92 pgs.)
☒ Drawings (Fig(s). 1 - 18b , 25 pgs.)
☒ Abstract of the Disclosure

- ☐ Executed Declaration/Power of Attorney
☒ Unexecuted Declaration/Power of Attorney
☐ Assignment/Assignment Recordation Form Cover Sheet (PTO-1595)
☐ Submission of Certified Copy of Priority Document w/ certified copy(ies)
☐ Preliminary Amendment
☐ Information Disclosure Statement Transmittal
☐ Information Disclosure Citation (PTO-1449)
☐ Information Disclosure Statement w/ document(s)
☐ Petition for Month Extension of Time
☐ Gen. Authorization for Petition for Ext. of Time and Pymt. of Fees
☐ Patent Application Data Sheet

- ☒ Check for \$ 4,370.00 is enclosed
☐ Check for \$ _____ is enclosed
☐ Charge \$ _____ to Deposit Account

If submitting documents via Express Mail, provide the Express Mailing Label No. below:
Express Mail Mailing Label No.

19270 U.S. PTO
10/763539

012604